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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,611	02/19/2002	Robert B. McCall	6205.N DV1	6307

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	13

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/078,611	Applicant(s) MCCALL ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003 and 06 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,11-18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,11-18 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendments filed May 12, 2003 and June 6, 2003 have been entered.

The outstanding rejections under 35 USC 112, second paragraph are withdrawn in view of the amendments filed May 12, 2003 and June 6, 2003.

Claims 7,8, 11-18 and 21-30 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 8, 11-18, and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moon et al. (US 5,273,975 from the IDS received June 19, 2002) in view of Gioco et al. (US Patent 5,565,466).

Moon et al. teaches a genus of compounds encompassing the elected compound herein to stimulate sexual behaviour in a dosage of 10 mg to 1200mg per day in multiple doses. (See col.2, line 10-24; col.9, line 58-65) Moon et al. also teaches the ED 50 dosage of the compounds to be 0.05mg/kg. (See col.9, line 40-45). Moreover, Moon et al. teaches the compounds can be administered orally. (See col.9, line 58-65). Furthermore, Moon et al. teaches the employment of pharmaceutically acceptable salts such as malate. (See col.10, line 6-14) The active compounds of Moon et al. encompass the elected compound herein: (5R)-5-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1-ij]quinoline-2(H)-thione. (See claim 1, for the compound in the formula if R_1=H, R2=CH3, R3=H, A= C=S, D= NH, and X=H).

Moon et al. does not expressly teach that the specific elected agent: (5R)-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1-ij]quinolin-2(1H)-thione is useful in method of increasing sexual desire, interest, or performance in human, particularly. Moreover, Moon et al. does not expressly teach the specific dosage range herein (recited in claims 16-18), the dosing regimen (recited in claims 22-24), and the exclusive conditions of the host to be treated i.e., one not having Parkinson's disease or not experiencing postural hypotension (recited in claims 25-26). Moon et al. does not expressly teach the combination of a secondary agent in the method to increase sexual desire, interest, or performance.

Gioco et al. teaches a method of modulating the excitory phase of female sexual response using vasodilating agents such as phentolamine (See particularly claims 14 and 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer (5R)-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1-ij]quinolin-2(1H)-thione to increase sexual desire, interest, or performance in human, at a specific time prior to sexual activity, and in an optimized dosage to a patient, wherein the patient does not experience postural hypotension and wherein the patient does not have Parkinson's. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a secondary agent in the same method.

One of ordinary skill in the art would have been motivated to administer the instant compound to a patient in increasing sexual desire, interest, or performance in human because the genus of compounds disclosed in Moon et al. are known to be useful to treat disorders including male erectile dysfunction. Therefore, all of the compounds of Moon et al. including: (5R)-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1-ij]quinolin-2(1H)-thione are reasonably expected to be useful to increase sexual desire, interest, or performance in human. In addition, Moon et al. teaches the effective dosage, e.g. 10mg per day in multiple doses, which is about 2-3mg per dose, similar to the herein claimed dosage. It is obvious as being within the skill of the artisan to optimize result effective therapeutic parameters (e.g. dosage range and dosing regimen) of the instant compound to maximize the therapeutic benefits to the patient and at the same time, eliminate unwanted effects, e.g. postural hypotension.

Furthermore, one of ordinary skill in the art would have been motivated to administer the instant compound to increase sexual desire, interest, or performance in

human, without regard to their medical status and/or condition, e.g., in having or not having Parkinson's disease. Similar therapeutic effects in the increase of sexual desire, interest, or performance in human would be reasonably expected whether or not the host also had (or suffered from) Parkinson's disease.

Finally, phentolamine is known to be useful as modulating the exciting phase of female sexual response. It flows logically to combine two agents together, which is known to be useful to stimulate or excite the sexual response individually, into a single method fore the very same purpose (See *In re Kerkhoven* 205 USPQ 1069). Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would be reasonably expected to employ phentolamine, with the elected compound herein, to increase or stimulate female sexual response and thereby increase the sexual desire, interest, or performance in human. .

Response to Arguments

Applicant's arguments filed May 12, 2003 averring the cited prior art's failure to teach the claimed utility have been considered, but are not found persuasive. Moon et al. clearly teaches the instant compounds are useful in a method to stimulate sexual behavior. Although the preferred compounds are not exemplified in Moon, the genus compounds still encompass the herein preferred compounds. In addition, Moon teaches the genus compounds herein. Therefore, absent evidence to the contrary, possessing the teachings of Moon, one of ordinary skill in the art would have been motivated to employ any compounds of Moon, including the instant preferred

compounds, in increasing the sexual desire, interest, or performance in human by stimulating the sexual behavior of the patient.

Applicant's arguments filed May 12, 2003 averring the dosage related to the route of administration taught in Moon is too toxic for treating sexual dysfunction have been fully considered but they are not persuasive. Please note that Moon et al. has taught the dosage as being administered in multiple times daily. For example, 5mg/dose twice daily will be equal to 10mg daily in multiple times of administration. Therefore, Moon still renders the instant claims obvious. Examiner notes that there is no claim recites the dosage as well as the route of administration together. As discussed in the parent application, which applicant filed the same declaration, the declaration filed May 12, 2003 merely pointing out the effective dose and ED_{50} of the selective compounds of Moon when they are administered orally [emphasis added]. Moon also teaches the ED_{50} is 0.05mg/kg when administered ip or sc (See col. 9, line 43). There is no claims recite both the dosage and the route of administration. Please note that claims 7, 8, 11-15, and 21-30 stand rejected because these claims are not limited by any dosage. Note also that claims 7, 8, 11-12, 16-18, and 21-30 are not limited to any route of administration. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been employing the herein claimed compounds in the method of increasing sexual desire, interest, or performance in human, absent evidence to the contrary.

Applicant's declaration filed May 12, 2003 in regard to the sexual dysfunction in Moon have been considered but are found to be relevant to the basis of rejection under 35 USC 103 set forth in the previous office action mailed November 2002.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617

SREENI PADMANABHAN
PRIMARY EXAMINER

9/16/03